

## **REMARKS**

Claims 76-77 have been canceled without prejudice or disclaimer. New claims 94-101 have been added. Support for the new claims can be found throughout the specification, including the previously presented claims. Claim 78 has been amended to correct an inadvertent typographical error. These amendments introduce no new matter.

Claims 67-75 and 78-101 are pending in the application, with claims 67, 78, 85 and 94 being the independent claims. Claims 78-93 have been withdrawn from consideration by the Examiner.

### **I. Statement of Substance of the Interview**

Applicants thank Examiners Stewart and Del Sole for the personal interview conducted on August 26, 2010, with Applicants' undersigned representatives. During the interview, the rejections of record were discussed, and consideration was asked to be given as to whether one reference would destroy the intended purpose of the other (corrective lens and hologram versus reflection hologram sensor in a lens). The Examiners also agreed that visually, Figure 2 of the present application (relating to at least claim 76) differs from the cited Figure 13 in Millington.

### **II. The Rejection of Claims 67, 68, 70, 71, 75 and 76 Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 67, 68, 70, 71, 75 and 76 have been rejected at pages 3-9 of the Office Action, as allegedly being obvious over Zhang *et al.*, WO 99/33642 (hereinafter "Zhang1") in view of Millington, US 2003/0103868 (hereinafter "Millington"). Applicants respectfully traverse this rejection.

The Office Action suggests that Zhang1 discloses a method for making a biocompatible contact lens containing a hologram comprising producing a recording a pattern of interference fringes while polymerizing/crosslinking a crosslinkable or polymerizable fluid in a cavity of a mold to form a holographic optical lens. The Office Action indicates that Zhang1 does not disclose that the holographic optical lens comprises a molecular sensing moiety which can

interact or react with an analyte of interest to provide an optical signal, or that the hologram is a reflection hologram.

The Office Action attempts to cure these deficiencies with the disclosure of Millington, suggesting that Millington discloses that a reflection hologram may be formed in contact lens and that a molecular sensing moiety can be incorporated in lens for use as an analyte sensor. The Office Action suggests that it would have been obvious to combine the disclosure of Zhang with that of Millington to provide a convenient way to detect changes in levels of biological substances. The Office Action therefore concludes that the claimed invention would have been obvious. Applicants respectfully disagree with these contentions and conclusions.

Applicants respectfully submit that the Office Action has not set forth a *prima facie* case of obviousness, as the modification proposed in the Office Action would render Zhang1 unsatisfactory for its intended purpose. As set forth in M.P.E.P. § 2143.01(V), “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

Zhang1 is directed to methods for producing corrective contact lenses. As set forth in Zhang1, “[t]he ophthalmic lens of the present invention utilizes the diffractive property of a holographic optical element (HOE), more particularly a transmissive volume HOE, to provide a corrective power.” Zhang1 at page 3, first full paragraph. Applicants submit that modifying the hologram utilized in the contact lenses of Zhang1 that provides “corrective power” to the reflective holograms disclosed in Millington, would destroy the ability of Zhang1 to provide correction to vision, and thus render Zhang1 inoperable for its intended purpose. As set forth in Millington, the holograms disclosed therein provide reflective signals that respond to the presence of absence of an analyte. There is no indication that such holograms could be utilized in the contact lenses of Zhang1 where the corrective properties of the holograms are required. Thus, a *prima facie* case of obviousness has not been established. See M.P.E.P. § 2143.01(V).

Finally, Applicants submit that there is no reasonable expectation that the holograms utilized in Millington could be applied to the contact lenses disclosed in Zhang1 and successfully

result in a corrective contact lens that also provides the analyte sensing set forth in Millington. As set forth in M.P.E.P. § 2143.02, absent a reasonable expectation of success, a *prima facie* case of obviousness cannot be established.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**III. The Rejection of Claims 69 and 77 Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 69 and 77 have been rejected at pages 9-10 of the Office Action, as allegedly being obvious over Zhang1 in view of Millington and further in view of Zhang *et al.*, U.S. 2002/0093701. Applicants respectfully traverse this rejection.

The Office Action suggests that Zhang1 and Millington disclose the claimed invention as set forth above. However, the Office Action concedes that the combination of references does not disclose partially crosslinking and/or polymerizing the crosslinkable and/or polymerizable fluid material by actinic irradiation before the producing and recording. The Office Action attempts to cure this deficiency with the disclosure of Zhang2, suggesting that this reference discloses such a processes. The Office Action therefore concludes that the claimed invention would have been obvious. Applicants respectfully disagree with these contentions and conclusions.

As discussed in detail above, Applicants submit that modification of Zhang1 with the disclosure of Millington would render Zhang1 inoperable for its intended purpose, and thus a *prima facie* case of obviousness has not been established. The disclosure of Zhang2 does not cure this deficiency, as there is no indication in Zhang2 that preparation of a reflection hologram in the contact lens of Zhang1 would still allow Zhang1 to provide a contact lens with corrective power. Thus, Applicants submit that, alone or in combination, Zhang 1, Millington and Zhang2 do not render obvious the presently claimed invention.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**IV. The Rejection of Claim 72 Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claim 72 has been rejected at pages 10-12 of the Office Action, as allegedly being obvious over Zhang1 in view of Millington and further in view of Asher *et al.*, U.S. 2003/0027240 (hereinafter “Asher”) and Kataoka *et al.*, *Macromolecules* 27:1061-1062 (1994) (hereinafter “Kataoka”). Applicants respectfully traverse this rejection.

The Office Action suggests that Zhang1 and Millington disclose the claimed invention as set forth above. However, the Office Action concedes that the references do not disclose that the molecular sensing moiety is a phenyl boronic acid having formula (4), (5) or (6), with the recited substituents. The Office Action attempts to cure this deficiency with the disclosures of Asher and Kataoka, suggesting that Asher discloses a sensor lens with a molecular sensing moiety comprising phenyl boronic acid, and that Kataoka discloses a boronic acid derivative of structure 4. The Office Action suggests that it would have been obvious to modify the combined disclosures and Zhang1 and Millington with the disclosures of Asher and Kataoka, and that therefore the claimed invention would have been obvious. Applicants respectfully disagree with these contentions and conclusions.

Applicants submit that modification of Zhang1 with the disclosure of Millington would render Zhang1 inoperable for its intended purpose, and thus a *prima facie* case of obviousness has not been established. The disclosures of Asher and Kataoka do not cure this deficiency, as there is no indication in these references that preparation of a reflection hologram in the contact lens of Zhang1 would still allow Zhang1 to provide a contact lens with corrective power. Thus, Applicants submit that, alone or in combination, Zhang 1, Millington, Asher and Kataoka do not render obvious the presently claimed invention.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**V. The Rejection of Claims 73-74 Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 73-74 have been rejected at pages 12-13 of the Office Action, as allegedly being obvious over Zhang1 in view of Millington and further in view of Müller, U.S. 5,508,317 (hereinafter “Müller”). Applicants respectfully traverse this rejection.

The Office Action suggests that Zhang1 and Millington disclose the claimed invention as set forth above. The Office Action concedes, however, that the combination of references does not disclose wherein the crosslinkable and/or polymerizable fluid material is an aqueous solution, which includes a low molecular weight additive that exhibits a limited compatibility with a polymer matrix resulted from the crosslinkable and/or polymerizable fluid material, but good compatibility with water, wherein the low molecular weight additive is present in an amount sufficient to increase refractive index differences ( $\Delta n$ ) between high and low irradiated areas resulted from the pattern of interference fringes. The Office Action attempts to cure this deficiency with the disclosure of Müller, indicating the Müller discloses the use of NaCl in the preparation of contact lenses to provide a salt solution with similar pH to that human lacrimal fluid. The Office Action therefore concludes that the claimed invention would have been obvious. Applicants respectfully disagree with these contentions and conclusions.

Applicants submit that modification of Zhang1 with the disclosure of Millington would render Zhang1 inoperable for its intended purpose, and thus a *prima facie* case of obviousness has not been established. The disclosure of Müller does not cure this deficiency, as there is no indication in this references that preparation of a reflection hologram in the contact lens of Zhang1 would still allow Zhang1 to provide a contact lens with corrective power. Thus, Applicants submit that, alone or in combination, Zhang 1, Millington and Müller do not render obvious the presently claimed invention.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**VI. The Rejection of Claims 67-71 and 75-77 Under 35 U.S.C. § 103(a) Should be Withdrawn**

Claims 67-71 and 75-77 have been rejected at pages 13-18 of the Office Action, as allegedly being obvious over Millington in view of Zhang2. Applicants respectfully traverse this rejection.

The Office Action suggests that Millington discloses a method of making a contact lens containing a reflection hologram, comprising producing a recording a pattern of interference fringes while polymerizing/crosslinking a polymerizable and/or crosslinkable fluid comprising a molecular sensing moiety. The Office action indicates, however, that Millington does not disclose the use of a mold having first and second halves. The Office Action attempts to cure this deficiency with the disclosure of Zhang2, suggesting that this reference discloses methods of making lenses with holograms utilizing molds. The Office action therefore concludes that it would have been obvious to combine the disclosures of Millington and Zhang2 so as to arrive at the claimed invention. Applicants respectfully disagree with these contentions and conclusions.

Applicants submit that Millington specifically requires the preparation of “a volume hologram sensor which provides a multiplicity of holographic images, where the set of images is multiplexed in the degree-of-freedom which is the dynamic detection range of the sensor.” Millington at page 1, paragraph [0005]. Applicants submit that there is not a reasonable expectation of success that the methods and molds disclosed in Zhang2 could be utilized to prepare the specifically required volume hologram sensors of Millington. Specifically, there is not a reasonable expectation that the cited combination of references could provide a multiplicity of holographic images, as required in Millington. As set forth in M.P.E.P. § 2143.02, absent a reasonable expectation of success, a *prima facie* case of obviousness cannot be established.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**VII. New Claims 94-101 Are Patentable Over the References Cited in the Office Action**

Applicants note that new claim 94 has been drafted based on previously presented claim 76. Present claim 94 recites a method for making a biocompatible sensor containing a reflection hologram. The method recites introducing a crosslinkable and/or polymerizable fluid material into a cavity formed by a mold, wherein the crosslinkable and/or polymerizable fluid material comprises at least a molecular sensing moiety which can interact or react with an analyte of interest to provide an optical signal which is indicative of a change in one or more optical properties of the reflection hologram. The mold has a first mold half defining a first molding surface and a second mold half defining a second molding surface, wherein the first mold half and said second mold half are configured to receive each other such that the cavity is formed between the first molding surface and said second molding surface, and wherein the second mold half has, on or behind the second molding surface, a mirror to reflect incident light coming from the first molding surface. A pattern of producing and recording a pattern of interference fringes are produced and recorded while polymerizing/crosslinking the crosslinkable and/or polymerizable fluid material in the cavity by directing an incident beam of coherent light through the first molding surface to the crosslinkable and/or polymerizable fluid material and to the mirror, wherein the incident beam and a beam reflected by the mirror form the pattern while polymerizing/crosslinking said crosslinkable and/or polymerizable fluid material to form the biocompatible sensor, whereby the pattern is recorded in said biocompatible sensor to form the reflection hologram.

Applicants submit that present claim 94 (and hence, claims 95-101 that depend ultimately therefrom) are not disclosed in any of the references cited in the Office Action. The Office Action suggests that previously presented claim 76 was allegedly disclosed in Millington in Figure 13 (*see* Office Action at pages 8-9, paragraph [0020]), or in Zhang2 at paragraph [0089] (*see* Office Action at page 18, paragraph 55). Applicants note that the methods disclosed in Millington and in Zhang2 both require the use of a beam splitter to separate the laser beam prior to being directed at the recording medium. Applicants submit that neither Millington nor Zhang2 discloses a method in which an incident beam of coherent light is directed *through a first molding surface* to the crosslinkable and/or polymerizable fluid material and *to the mirror*, wherein *the incident beam (i.e., the same beam that passed through the first molding surface)*

*and a beam reflected by the mirror form the pattern while polymerizing/crosslinking the crosslinkable and/or polymerizable fluid material to form the biocompatible sensor, whereby the pattern is recorded in the biocompatible sensor to form the reflection hologram.*

As set forth in the Interview Summary, Examiners Stewart and Del Sole also agreed that visually, Figure 2 of the present application (relating to at least claim 76) differs from the cited Figure 13 in Millington. Thus, Applicants submit that claims 94-10 are not disclosed or otherwise rendered obvious by the references cited in the Office Action.



**VIII. Conclusion**

Applicants believe that the claims of the present application are in condition for allowance and respectfully request allowance thereof. The Examiner is invited to telephone the undersigned if that would be helpful in resolving any issues.

With the exception of extension of time fees, no fees are believed due for this submission. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application or credit any overpayment, to Deposit Account No. 50-5071. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-5071.

Respectfully submitted,

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